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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/09/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/732,436	PRAYAGA ET AL.
Examiner	Art Unit	
Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 April 2003 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1 and 42-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 42-45 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____ .

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

4) Interview Summary (PTO-413) Paper No(s) _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____ .

DETAILED ACTION

Response to Amendment

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 55-58 have been renumbered 42-45.2. Claim 1 has been amended, claims 2-41 have been cancelled and claims 42-45 have been added as requested in the amendment of Paper No. 28, filed on April 04, 2003. Claims 1 and 42-45 are pending in the instant application.

Claims 1 and 42-45 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on April 04, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Sequence compliance

6. Applicant has failed to provide a statement that the content of the substitute paper and computer readable copies of the "Sequence Listing" are the same and include no new matter, as

required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). Appropriate action is required.

Specification

7. It appears that Applicant misunderstood the content of section 3 of Paper No. 26 regarding proper use of trademarks in patent application (see page 5, second paragraph of the Response). The requirement was not to check for trademarks in the text of the instant specification but rather to correct the presentation of a trademark, which is “It should be capitalized wherever it appears and be accompanied by the generic terminology”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

8. Claims 1 and 42-45 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record as applied to claims 1-4 in section 5 of Paper No. 26. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on premises “that at least one substantial and specific utility exists for the claimed invention and is readily apparent based on the teachings of the specification. Applicants respectfully assert that the claimed protein, SEQ ID NO: 6, is

differentially expressed in the temporal cortex of Alzheimer's disease patients when compared to non-demented controls and is useful, *inter alia*, as a marker (diagnostic indicator) for Alzheimer's disease" (bottom at page 6 of the Response). Applicant refers to the instant specification at page 21, line 3 to page 22, line 16 and to exhibit A of the Response for comparison of quantitative gene expression analyses of SEQ ID NO: 6. Applicant's arguments and information in Exhibit A have been carefully considered but are not deemed persuasive for the following reasons.

First, the Examiner fails to find support for asserted utility of the claimed polypeptide as a marker for Alzheimer's disease within the instant specification at the above noted passages. Next, according to Applicant's statement "Exhibit A shows that SEQ ID NO: 6 is found to be down-regulated in the temporal cortex of Alzheimer's disease patients" (page 7, second paragraph of the Response). However, the average level of expression of SEQ ID NO: 6 polypeptide in the eight AD temporal cortex samples equals to 42.06, while average of eight control corresponding samples is 34.91. Therefore, it appears that the instant claimed polypeptide of SEQ ID NO: 6 is upregulated rather than down regulated in temporal cortex tissue of AD patients. Nevertheless, the instant specification, as originally filed, failed to provide any evidence or sound scientific reasoning that the instant claimed polypeptide of SEQ ID NO: 6 can be used as a marker for Alzheimer's disease. Therefore, any subsequent data regarding possibility of using the instant polypeptide as a marker for AD is not considered to be persuasive. 35 USC § 101 clearly states that the invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly “the metes and bounds” of which “are not capable of precise delineation”. That monopoly “may engross a vast, unknown, and perhaps unknowable area” and “confer power to block off whole areas of scientific development, without compensating benefit to the public” *Brenner v. Manson, Ibid*). Because the instant specification does not disclose a credible “real world” use for the claimed polypeptide then the instant invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

9. Claims 1 and 42-45 are also rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 1-4 in section 6 of Paper No. 26. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Claims 44 and 45 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 1-4 in section 7 of Paper No. 26.

Claim 44 is directed to an isolated polypeptide, which is 99% identical to the amino acid sequence of SEQ ID NO: 6. Claim 45 depends from claim 44. However, the instant specification

fails to describe the entire genus of proteins, which are encompassed by these claims. The instant specification only describes a polypeptide of SEQ ID NO: 6 and fails to describe any other polypeptide that lacks this sequence and has the functional characteristics of a polypeptide of SEQ ID NO: 6. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the protein of SEQ ID NO: 6. The specification does not provide a complete structure of those polypeptides, which are 99% identical to the amino acid sequence of SEQ ID NO: 6. The claims fail to recite other relevant identifying characteristics, physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure, or to provide a representative number of species for the claimed genus sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.

Conclusion

11. No claim is allowed.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

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Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*
June 6, 2003



JOHN ULM
PRIMARY EXAMINER
GROUP 1800